

## PATENT COOPERATION TREATY

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## NOTIFICATION OF ELECTION

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| <b>Date of mailing</b> (day/month/year)<br>25 February 1998 (25.02.98)       |  |
| <b>International application No.</b><br>PCT/NL97/00404                       | <b>Applicant's or agent's file reference</b><br>39810.01 nm      |
| <b>International filing date</b> (day/month/year)<br>09 July 1997 (09.07.97) | <b>Priority date</b> (day/month/year)<br>12 July 1996 (12.07.96) |
| <b>Applicant</b><br>DE HEUS, Evert, Bastiaan                                 |  |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
30 January 1998 (30.01.98)

☐ in a notice effecting later election filed with the International Bureau on:  
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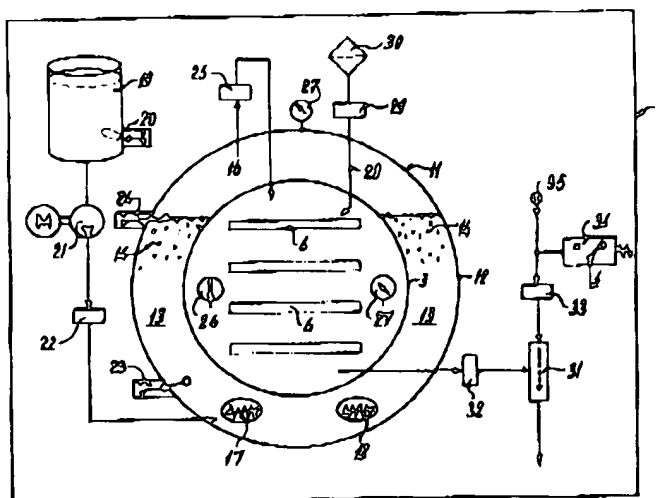
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International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|   |  |   |
|---|--|---|
| (51) International Patent Classification 6:<br><b>A61L 2/06</b>   |  | (11) International Publication Number:<br><b>WO 98/02193</b>  |
| A1  |  | (43) International Publication Date: 22 January 1998 (22.01.98)   |
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| (71) Applicant (for all designated States except US): HEVO N.V. [BE/BE]; Nicuwateraat 12, B-2382 Poppel (BE).     |  |   |
| (71)(72) Applicant and Inventor: DE HEUS, Evert, Bastiaan [NL/NL]; Leeghwaterstraat 4, NL-4251 LM Werkendam (NL). |  |   |
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(54) Title: STERILISATION APPARATUS



## (57) Abstract

Sterilisation apparatus, for medical instruments and similar objects, which is easy to handle and/or remove and which is mainly formed by a casing (1) provided with a sterilisation boiler (11) and means for performing the sterilisation process. The sterilisation apparatus comprises a double-walled boiler (11) whereby fluid (13), such as demineralised water, which is present between the inner wall (3) and the outer wall (12), is heated by heating elements (17, 18) so as to achieve a stable temperature of the boiler wall as well as to generate steam (16). The apparatus further comprises a water reservoir (19), pump (21) and valve (22) for supplying water to the boiler and means (23, 24) for controlling the level of water, a valve (25) through which generated steam (16) can be injected into the sterilisation chamber, a water-ejector (31) for drawing a vacuum in the chamber, and an aeration valve (29) for releasing the vacuum.

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300 Rec'd PCT/PTC 12 JAN 1999

## STERILISATION APPARATUS

5 The invention relates to a sterilisation apparatus for medical instruments and the like objects, which is easy to handle and/or remove and which is mainly formed by a casing provided with a sterilisation boiler and means for performing the sterilisation process.

10 Such a sterilisation apparatus, also called a mini sterilisation apparatus, is often used in dentists' practices. The contents of the sterilisation apparatus thereby range between 10 to 50 litres and the required temperatures often are between 121 degrees C and 134 degrees C at pressures of ca. 210 kPa and 310 kPa, respectively.

15 A problem relating to this mini sterilisation apparatus is that one can barely, if at all, comply with the (international) requirement of obtaining a stable ambient temperature of the sterilisation boiler during sterilisation.

20 The invention overcomes this problem since the sterilisation apparatus comprises a double-walled boiler whereby fluid such as demineralised water being present between the inner and the outer wall by which a stable temperature of the boiler wall can be achieved as well as steam generated therefrom. This makes the sterilisation process very well manageable in a relatively small sterilisation apparatus, as also shown in practice.

25 It is thereby advantageous that at least regulators and heating elements in said double boiler walls can provide for a stable fluid temperature.

30 Advantage is offered by the embodiment according to the invention in which means are present for feeding steam for the sterilisation process pulsatingly into said boiler, as well as means which can also provide a pulsating vacuum in said boiler such that air in the instruments or the like objects which are to be sterilised can be removed.

35 To make the sterilisation process occur automatically the sterilisation apparatus is provided with means for setting, respectively measuring pressure, temperature, time and output for controlling all phases occurring within said boiler before, during and after the sterilisation process. These means are preferably controlled by a process computer which displays various data read-outs digitally and/or alphanumerically and/or graphically, e.g. to an internal or external printing apparatus (printer).

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Especially in a dentist's practice where an autoclave will be used intensively it may be desirable to provide a mini sterilisation apparatus with a (time) switch clock for use of "stand-by" purposes, such as for heating-up of and maintaining the temperature of the boiler.

5 Advantage is offered by the embodiment of a mini sterilisation apparatus according to the invention which is characterized in that the sterilisation space of the boiler is provided with lateral supports for a number of standard plateaus on which instruments, whether wrapped or not, and/or bandage substances may be placed.

10 For effective use it is desirable that in the mini sterilisation apparatus according to the invention the front or feed side of the boiler can be sealed pressure-tight by means of a heat-isolating hinged door provided with an incorporated nut whereby the casing to that end is provided with a swivelable hermetically sealing screw. The screw seal is prefeably operated by means of an electromotor of which the operating phases are run via said process computer.

15 In order to comply with the procedure required of process sterilisation, according to the invention use is made of a sterilisation boiler for incorporation in a mini sterilisation apparatus which is characterized in that a cylindrical sterilisation boiler is placed symmetrically though non-concentrically within the cylindrical outer boiler, such that in the use-position the volume of the fluid or water space down in the double-walled boiler is considerably larger than up in the boiler.

20 It is advantageous if this sterilisation boiler is provided in a casing in which also the fluid reservoir with corresponding pump, control appendages, a dry-air connection and a connection to a vacuum line with valves being present.

25 The invention is hereinafter described by means of examples of embodiments, whereby advantages and other features of the invention will become apparent.

30 Figure 1 shows a perspective view of a mini sterilisation apparatus; figure 2 shows a block scheme of the most important operational functions of the sterilisation apparatus;

35 figure 3 shows, according to a computer drawing, another embodiment of the sterilisation apparatus.

Figure 1 shows in perspective a front view of the sterilisation apparatus, in fact the casing 1 thereof, which has a mainly rectangular

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shape and is made of suitable plate material. The front side shows a door 2 which can be swivelled open over more than 120 degrees and which further is well isolated against heat loss. Opening and closing the door occur automatically by activating an electrical operating button (not drawn). The opened door depicts a (inner) boiler 3 of which the space 4 in this embodiment is provided with four bearing plateaus 6, so-called norm trays, on which (wrapped) instruments or bandage substances can be transported. To that end space 4 is provided with supports 5. Door 2, which can seal sterilisation space 4, is fixed pressure-tight in the closed position by an electrically driven screw-seal 7 and cannot be opened during a sterilisation process. During a process the LCD screen 8 graphically displays the course of this process.

The sterilisation apparatus moreover comprises a process computer of which the control 9 is embodied with an indication for each process phase. The pressure, temperature, sterilisation time, drying time and possible malfunctioning are displayed digitally, eventually supported alpha-numerically or graphically. The pressure in the so-called steam generator is, as prescribed, displayed analogously on indicator 10.

Figure 2 schematically shows the sterilisation boiler 11 with various auxillary parts and control apparatuses, which parts are described hereinafter.

It is to be noted that similar references are used for similar parts.

Boiler 11 according to the invention comprises an inner wall and an outer wall, 3 respectively 12, whereby the contents of the inner boiler range between 10 to 50 litres. Demineralised water (demi-water) 14 added to space 13 of the double boiler wall 3, 12 is heated such that steam 16 is produced at the top of the boiler. Heating of the water occurs through heating elements 17, 18 which have been provided in boiler space 13. For the provision of water the sterilisation apparatus comprises a water reservoir 19 onto which a floating switch 20 for level control is provided. In this arrangement a feed pump 21 is applied by means of which water down in space 13 of the double boiler wall 3, 12 can be supplied. A shut-off valve 22 for pumping water for boiler space 13 is provided in the pump circuit. As already indicated above, heating elements 17, 18 are provided at the bottom of boiler 3, 12 by means of which the water supplied can be heated, such that steam 16 is formed at the top for the purpose of the sterilisation process. A safety switch 23 with a float embodiment for protection against dry-boiling is provided at the bottom of the boiler. A

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water level controller 24 is present at the top so that the proper ratio between steam and water is always obtained. The generated steam 16 is supplied pulsatingly from boiler space 13 through a steam valve 25 into the inner boiler 3. Further, there is a temperature measuring device 26 as well as a pressure transmitter within inner boiler 3. A similar transmitter is also provided in the outer boiler 12. In figure 2 the left-hand side depicts the water and steam system and the right-hand side depicts the vacuum system. Thereby a feed line 28 is provided at the top side of the boiler, in which an aeration valve 29 is provided for feeding clean air when a vacuum is prevailing in the boiler. For the sake of certainty a sterile filter 30 provides for clean air when feeding to valve 29.

According to the invention a vacuum is drawn pulsatingly in the boiler, which is achieved by using a water-ejector system which mainly comprises an ejector 31 connected to a vacuum valve 32 which is connected through a line to inner boiler 3. A cold-water valve 33 is incorporated in the water system of ejector 31 which serves for generating a vacuum through ejector 31. Further a pressure switch 34 for measuring the water pressure is used in the line system, by which water is tapped-off from feed 35.

The following gives a brief illustration of a sterilisation process at a temperature of 134 degrees C. A process can only start if door 2 is closed, and the process begins with steaming-through whereby valves 25, 33 and 32 are opened. Valves 33 and 32 of the ejector system remain open during steaming-through. Steam valve 25 is thereby regulated at a pressure of 120 kPa within inner boiler 3. During a certain period, about 90 seconds, there is a continuous discharge of steam and air. After this period of 90 seconds steam valve 25 closes and the first vacuum pulse starts. The pulsating course of the process occurs further by successively controlling the valves concerned, the build-up of pressure as well as the time in seconds, so that the sterilisation pressure and temperature are achieved in an effective manner within the stated period. In this example a temperature of 134 degrees C to a maximum of 137 degrees C is achieved in about 15 seconds. Pressure control in the boiler is achieved by a autonomously functioning control process. However, in case during the sterilisation process the temperature and/or the pressure exceeds the maximum set value, the process is automatically broken off.

After the sterilisation traject drying of the objects present on plateaus 6 takes place by drawing a vacuum. To this end steam valve 25

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is shut and cold-water valve 33 as well as vacuum valve 32 are opened, till a pressure of 10 kPa is reached. At this pressure the actual drying time starts, which lasts 5 minutes in this process (134 degrees C). After drying the boiler is aerated to relieve the vacuum. If the drying process is terminated, valves 32 and 33 are shut. When the boiler pressure lies between 95-105 kPa, aeration valve 29 shuts due to which door 2 can be opened and the sterilised objects can be removed from boiler space 4.

As stated above, the whole process takes place under the control of and monitoring by a computer and the results are displayed by means of a printing device, a so-called printer (not shown).

Figure 3 depicts another advantageous embodiment according to the invention in which in particular the water reservoir 13 has been enlarged by the positioning of inner boiler 3 relative to outer boiler 12, i.e. that the amount of water at the bottom of boiler 11 is greater than the amount at the top thereof, which may be favourable for certain sterilisation processes in view of the water-steam ratio.

The invention is not limited to the embodiments as shown and described above, since one can well imagine other arrangements of sterilisation boilers. The feature according to the invention of using a double boiler wall in a relatively small sterilisation apparatus has however resulted in the fact that such a sterilisation apparatus can comply with the highest standards, including international standards.



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CLAIMS

- 5 1. Sterilisation apparatus for medical instruments and the like objects which is easy to handle and/or remove and which is mainly formed by a casing provided with a sterilisation boiler and means for performing the sterilisation process, characterized in that the sterilisation apparatus comprises a double-walled boiler whereby fluid such as demineralised water being present between the inner and the outer wall by which a stable temperature of the boiler wall can be achieved as well as steam generated therefrom.
- 10
- 15 2. Apparatus according to claim 1, characterized in that at least regulators and heating elements in said double boiler walls can provide for a stable fluid temperature.
- 20 3. Apparatus according to claim 1 or 2, characterized in that means are present for feeding steam for the sterilisation process pulsatingly into said boiler, as well as means which can also provide a pulsating vacuum in said boiler such that air in the instruments or the like objects which are to be sterilised can be removed.
- 25 4. Apparatus according to any of preceding claims 1-3, characterized in that means are present for setting, respectively measuring pressure, temperature, time and output for controlling all phases occurring within said boiler before, during and after the sterilisation process.
- 30 5. Apparatus according to claim 4, characterized in that the means are controlled by a process computer which displays various data read-outs digitally and/or alphanumerically and/or graphically, e.g. to an internal or external printing apparatus (printer).
- 35 6. Apparatus according to any of the preceding claims, characterized in that a (time) switch clock for use of "stand-by" purposes, such as for heating-up of and maintaining the temperature of said boiler, is available.
7. Apparatus according to any or several of the preceding claims, characterized in that the sterilisation space of the boiler is provided with

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lateral supports for a number of standard plateaus on which instruments, whether wrapped or not, and/or bandage substances may be placed.

- 5        8.        Apparatus according to any or several of the preceding claims, characterized in that the front or feed side of the boiler can be sealed pressure-tight by means of a heat-isolating hinged door provided with an incorporated nut whereby the casing to that end is provided with a swivelable hermetically sealing screw.
- 10       9.        Apparatus according to claim 8, characterized in that the screw seal is operated by means of an electromotor of which the operating phases are run via said process computer.
- 15       10.       Apparatus according to any or several of the preceding claims, characterized in that a cylindrical sterilisation boiler is placed symmetrically though non-concentrically within the cylindrical outer boiler, such that in the use-position the volume of the fluid or water space down in the double-walled boiler is considerably larger than up in the boiler.
- 20       11.       Apparatus according to any or several of preceding claims 1-9, characterized in that a cylindrical sterilisation boiler is placed concentrically within a cylindrical outer boiler.
- 25       12.       Apparatus according to any of preceding claims 1-9, characterized in that the process computer and a sterilisation apparatus according to claim 10 or 11 are provided in a casing in which also the fluid reservoir with corresponding pump, control appendages, a dry-air connection and a connection to a vacuum line with valves being present.

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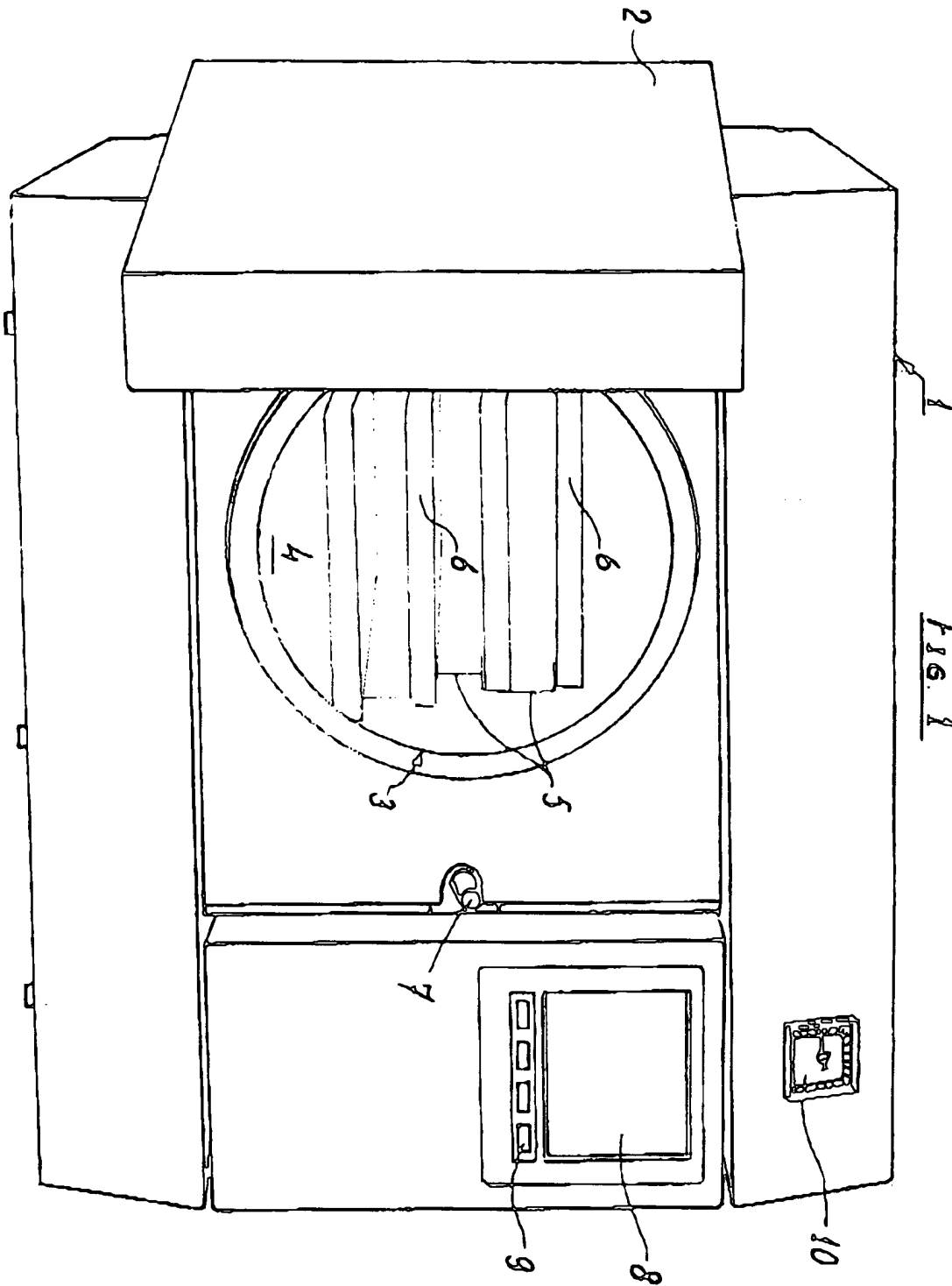


Fig. 1

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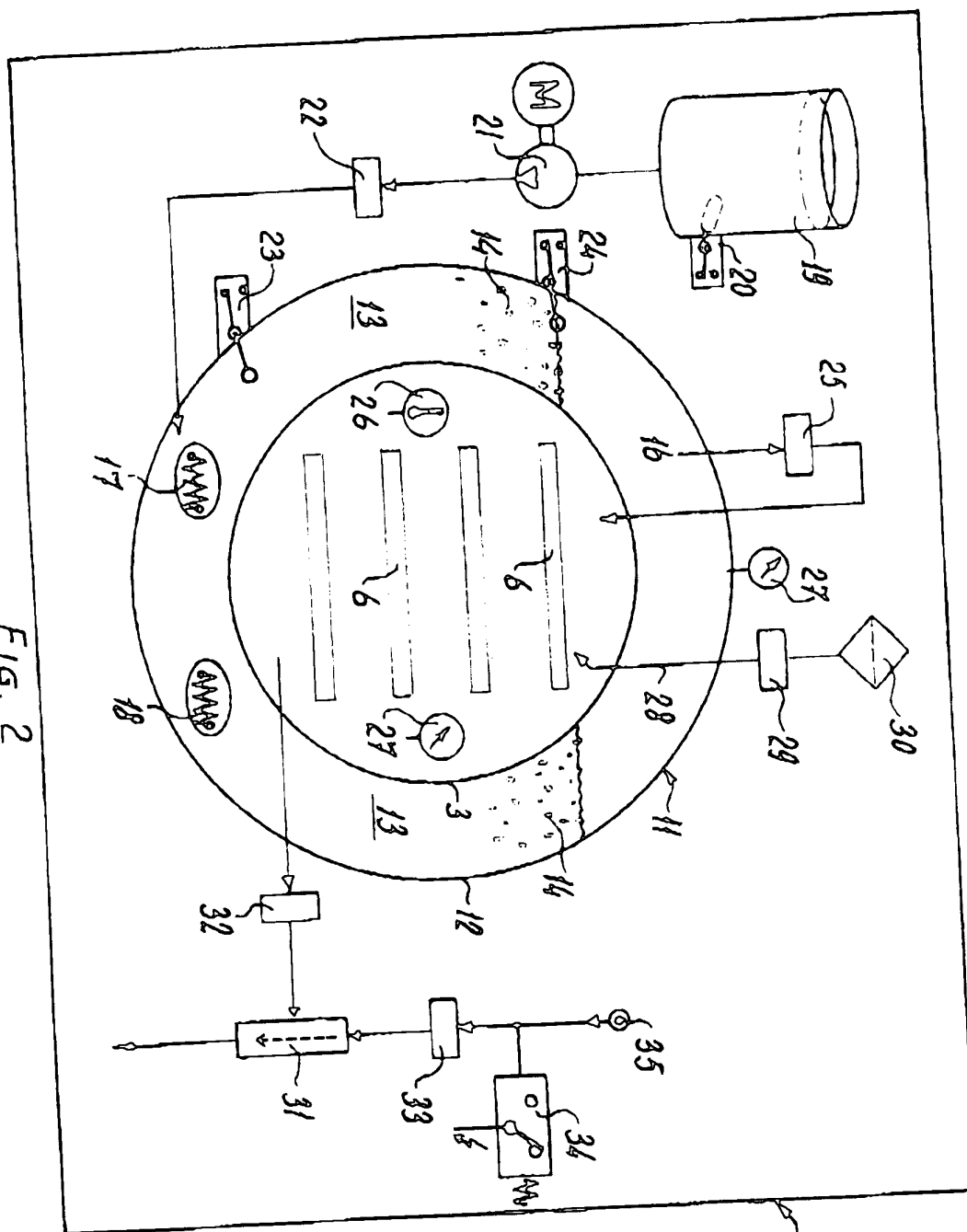
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FIG. 2



SUBSTITUTE SHEET (RULE 26)

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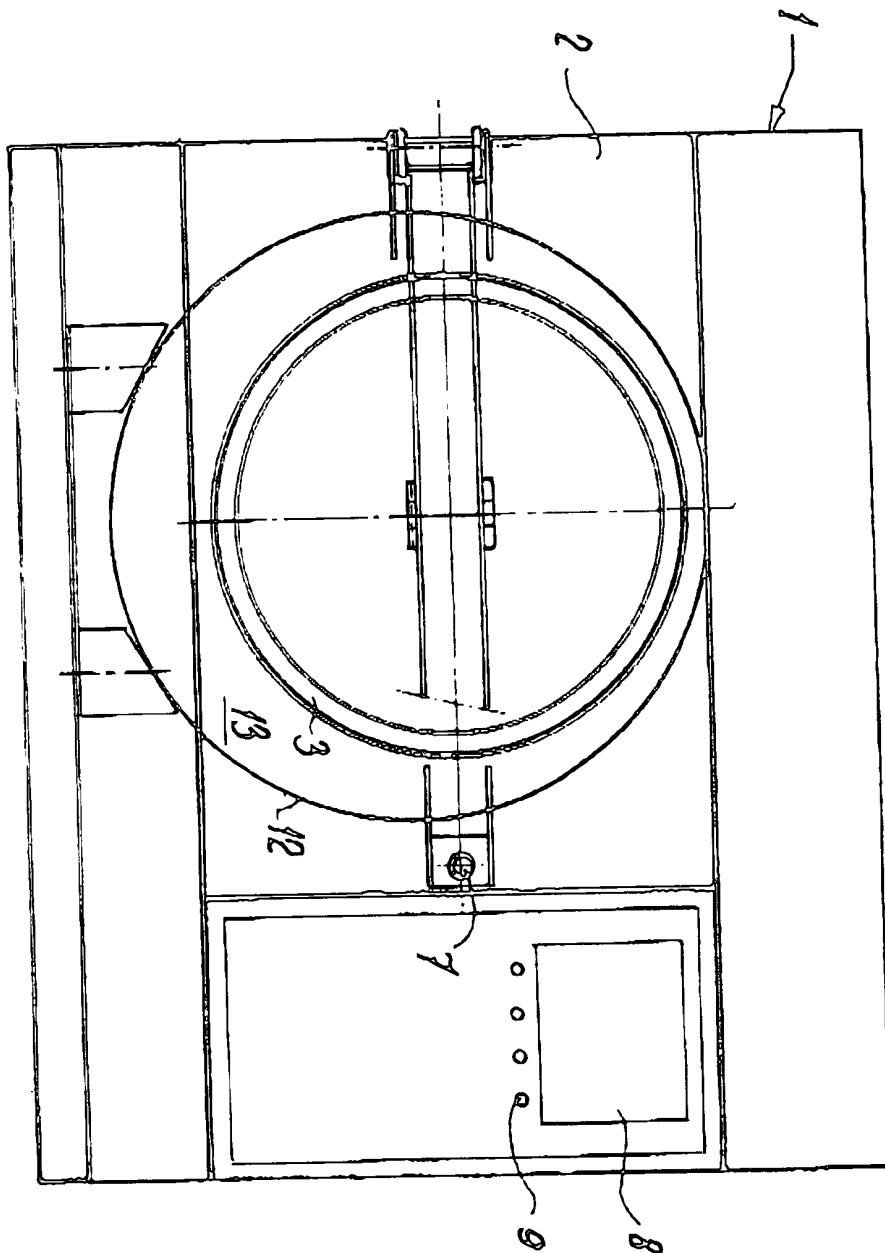


FIG. 3

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## INTERNATIONAL SEARCH REPORT

Int. Patent Application No.

PCT/NL 97/00404

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61L2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                           | Relevant to claim No. |
|------------|--|-----------------------|
| X          | DE 29 25 034 A (VEREINIGTE EDELSTAHLWERKE (VEW)) 7 February 1980<br>see the whole document<br>---            | 1-4                   |
| X          | FR 889 067 A (F. LAUTENSCHLAGER) 30 December 1943<br>see the whole document<br>---                           | 1-3,7,11              |
| X          | DE 14 92 497 A (K.A.O. WALLDEN) 2 October 1969<br>see page 11, paragraph 1 - paragraph 2;<br>figure 5<br>--- | 1,2,11                |
| X          | DE 904 237 C (F. LAUTENSCHLAGER) 15 February 1954<br>see the whole document<br>---                           | 1,2,11                |
|            | -/-  |                       |

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search

18 November 1997

Date of mailing of the international search report

24.11.97

Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

h. International Application No.

PCT/NL 97/00404

## C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                                  | Relevant to claim No. |
|------------|---|-----------------------|
| X          | US 5 103 076 A (M. HOUKUWA) 7 April 1992<br>see the whole document<br>---   | 1,2,7                 |
| A          | EP 0 492 056 A (SIEMENS) 1 July 1992<br>see page 4, column 5, line 24 - page 5,<br>column 7, line 38; figure<br>--- | 1,3-7,12              |
| A          | WO 92 01479 A (MIDMARK CORP.) 6 February<br>1992<br>see page 6, line 13 - line 26; claims<br>-----                  | 1,4-9                 |

## INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Search Report No.

PCT/NL 97/00404

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)   | Publication<br>date                                      |
|---|---------------------|--|--|
| DE 2925034 A                              | 07-02-80            | AT 358182 A<br>CH 641961 A<br>NL 7905838 A<br>SE 7906195 A<br>US 4263258 A | 25-08-80<br>30-03-84<br>30-01-80<br>29-01-80<br>21-04-81 |
| FR 889067 A                               | 03-01-44            | NONE   |  |
| DE 1492497 A                              | 02-10-69            | NONE   |  |
| DE 904237 C                               |                     | NONE   |  |
| US 5103076 A                              | 07-04-92            | AU 3543789 A<br>WO 8911332 A   | 12-12-89<br>30-11-89                                     |
| EP 0492056 A                              | 01-07-92            | US 5196165 A<br>DE 69123032 D<br>DE 69123032 T<br>JP 4295367 A             | 23-03-93<br>12-12-96<br>10-04-97<br>20-10-92             |
| WO 9201479 A                              | 06-02-92            | US 5223229 A<br>AU 8052791 A<br>CA 2086929 A<br>EP 0539389 A               | 29-06-93<br>18-02-92<br>20-01-92<br>05-05-93             |



## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

|  |  |  |
|--|--|--|
| Applicant's or agent's file reference<br>39810.01 nm                                     | <b>FOR FURTHER ACTION</b>                                | See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416) |
| International application No.<br>PCT/NL97/00404  | International filing date (day/month/year)<br>09/07/1997 | Priority date (day/month/year)<br>12/07/1996   |
| International Patent Classification (IPC) or national classification and IPC<br>A61L2/06 |  |  |
| Applicant<br>HEVO N.V.   |  |  |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

|   |   |
|---|---|
| Date of submission of the demand<br><br>02/02/1998  | Date of completion of this report<br><br>15.10.98   |
| Name and mailing address of the IPEA/<br><br> European Patent Office<br>D-80298 Munich<br>Tel. (+49-89) 2399-0. Tx: 523656 epmu d<br>Fax: (+49-89) 2399-4465 | Authorized officer<br><br>Katsoulas, K<br><br>Telephone No. (+49-89) 2399-8613<br> |

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/NL97/00404

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

2-5 as originally filed

1,1a as received on 16/07/1998 with letter of 13/07/1998

**Claims, No.:**

1-10 as received on 16/07/1998 with letter of 13/07/1998

**Drawings, sheets:**

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/NL97/00404

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

|                               |                    |
|-------------------------------|--------------------|
| Novelty (N)                   | Yes: Claims 1-10   |
|                               | No: Claims         |
| Inventive step (IS)           | Yes: Claims 2,9,10 |
|                               | No: Claims 1,3-8   |
| Industrial applicability (IA) | Yes: Claims 1-10   |
|                               | No: Claims         |

**2. Citations and explanations**

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

---

International application No. PCT/NL97/00404

D2: DE-A-1492497; D4: WO 92/01479

**Ad Section V:**

1. D2 discloses (cf. fig. 5 and related description) a sterilisation apparatus comprising a horizontal double walled boiler with water between the walls, which is heated by a heating element (43). Steam is generated and transported (22') into the inner volume of the boiler. A steam regulator 19' is also present and at least the inner boiler can have a hollow cylindrical shape (page 11, last paragraph). It follows that claim 1 differs from the above disclosure in that (i) the outer boiler is also cylindrical and (ii) a process computer is installed in the casing. The first difference is considered as an obvious possible structural arrangement and the second as an obvious measure to achieve system independence. It is also noted that these new features do not comprise any synergistic effect and that in-casing process computers are already known (cf D4). Thus, claim 1 does not meet the requirements of Art. 33(3) PCT.
2. The additional features of claims 3-8 are considered as obvious possibilities available to a skilled person once faced with the corresponding problem, in particular in view of the combined teaching of D2 and D4. Thus, no inventive step can be acknowledged for these claims (Art. 33(3) PCT).
3. The additional features of dependent claims 2 and 9,10 give rise to feature combinations which are neither known nor rendered obvious by the available art in solving the corresponding problem. Thus, these claims meet the requirements of Art. 33(3) PCT.

**Ad Section VII:**

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D2 and D4 are not mentioned in the description, nor are these documents identified therein.

**Ad Section VIII:**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

---

International application No. PCT/NL97/00404

1. In claim 1 the clause "for medical instruments and the like objects which is (are) easy to handle and/or remove" is purely indicative of intent and does not restrict the claimed scope to any particular apparatus size, as for example to a mini sterilisation apparatus having a content of 10 - 50 litres, as indicated on page 1. It is noted that larger known sterilisation apparatuses (cf D1, D2) are also capable of sterilising such items.
2. In claim 1 the presence of a fluid between the boiler walls is indicated. This term encompasses liquids as well as gases. Since claim 1 appears to require the production of steam which requires water and the description does not support the use of any fluid other than water, claim 1 is not clear (Art. 6 PCT). In this respect it is further noted that the presence of the fluid between the walls is not explicitly stated as a structural feature of the claimed apparatus (cf also claim 9). Art. 6 PCT.
3. On page 5 lines 18, 19 of the description, the statement "one can well imagine other arrangements of sterilisation boilers" makes the scope of the claims ambiguous (Art. 6 PCT). This applies also to the term "preferably" on page 1a line 12, in relation to the use of a process computer.
4. On page 4 line 37, the term "traject" cannot be understood.

PCT

29.08.97

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

PCT/NL 97 / 00404

International Application No.

09 JUL 1997

09.07.97

International Filing Date

BUREAU VOOR DE INDUSTRIËLE EIGENDOM  
P.C.T. INTERNATIONAL APPLICATION

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference  
(if desired) (12 characters maximum)

39810.01 nm

|  |   |   |                         |   |
|--|---|---|-------------------------|---|
| Box No. I  | TITLE OF INVENTION  |   | Sterilisation apparatus |   |
| Box No. II   | APPLICANT   |   |                         |   |
| Name and address:  |   | (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)  |                         | <input type="checkbox"/> This person is also inventor.  |
| HEVO N.V.<br>12 Nieuwstraat<br>2382 Poppel<br>Belgium  |   |   |                         | Telephone No.<br><br>Facsimile No.<br><br>Teleprinter No.   |
| State (i.e. country) of nationality:   |   | State (i.e. country) of residence:  |                         |   |
| Belgium  |   | Belgium   |                         |   |
| This person is applicant for the purposes of:  |   | <input type="checkbox"/> all designated States<br><input checked="" type="checkbox"/> all designated States except the United States of America<br><input type="checkbox"/> the United States of America only<br><input checked="" type="checkbox"/> the States indicated in the Supplemental Box |                         |   |
| Box No. III  | FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)             |   |                         |   |
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| de HEUS, Evert Bastiaan<br>4, Leeghwaterstraat<br>4251 LM Werkendam<br>The Netherlands   |   |   |                         |   |
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| The Netherlands  |   | The Netherlands   |                         |   |
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| Name and address:  |   | (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)  |                         | Telephone No.<br>070-3200565<br>Facsimile No.<br>070-3202824<br>Teleprinter No.   |
| Merkelbach, B<br>postal address: 47, van Ruysdaellaan<br>2264 TK Leidschendam<br>The Netherlands   |   |   |                         |   |
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## Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

## Regional Patent

- ☐ **AP ARIPO Patent:** KE Kenya, MW Malawi, SD Sudan, SZ Swaziland and any other State which is a Contracting State of the Harare Protocol and of the PCT
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- ☐ **OA OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line) .....

## National Patent (if other kind of protection or treatment desired, specify on dotted line):

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In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of .....

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

**Box No. VI PRIORITY CLAIM**Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

| Country<br>(in which, or for which, the<br>application was filed) | Filing Date<br>(day/month/year) | Application No. | Office of filing<br>(only for regional or<br>international application) |
|---|---------------------------------|-----------------|---|
| item (1)<br>The Netherlands                                       | 12 July 1996<br>(12.07.1996)    | 1003576         | <del>BIE RIJSWIJK</del>   |
| item (2)  |                                 |                 |   |
| item (3)  |                                 |                 |   |

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s) : \_\_\_\_\_
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**Choice of International Searching Authority (ISA)** (If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used): ISA / \_\_\_\_\_

**Earlier search** Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request:

Country (or regional Office): \_\_\_\_\_ Date (day/month/year): \_\_\_\_\_ Number: \_\_\_\_\_

**Box No. VIII CHECK LIST**

This international application contains the following number of sheets:

1. request : 3 sheets  
 2. description : 6 sheets  
 3. claims : 3 sheets  
 4. abstract : 1 sheets  
 5. drawings : 3 sheets

Total : 16 sheets

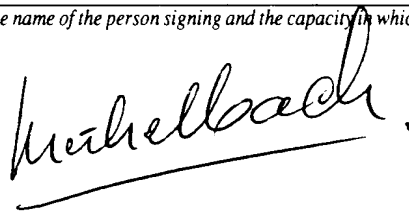
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 2. ☐ copy of general power of attorney  
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 5. ☐ fee calculation sheet  
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Figure No. 1 of the drawings (if any) should accompany the abstract when it is published.

**Box No. IX SIGNATURE OF APPLICANT OR AGENT**

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).



B. Merkelbach

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|   |   |
|---|---|
| 1. Date of actual receipt of the purported international application:<br><b>09 JUL 1997</b> (09.07.97)                                      | 2. Drawings:<br><input checked="" type="checkbox"/> received:<br><br><input type="checkbox"/> not received: |
| 3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application: |   |
| 4. Date of timely receipt of the required corrections under PCT Article 11(2):  |   |
| 5. International Searching Authority specified by the applicant: ISA /  | 6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid                     |

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Date of receipt of the record copy by the International Bureau: **24 JULY 1997** (24.07.97)





## Sterilisation apparatus

The invention relates to a sterilisation apparatus for medical instruments and the like objects which is easy to handle and/or remove consisting of a casing with a sterilisation chamber mainly comprising of a double-walled boiler whereby fluid such as demineralised water being present between an inner and outer wall of said boiler and means for performing the sterilisation process such as regulators and heating elements by means of which temperature and steam generated therefrom are controlled.

The German patent 904237 discloses such a sterilisation apparatus.

The Sterilisation apparatus according to the invention concerns a mini-sterilisation apparatus which is often used in dentists' practices. The content of this type of apparatus is in the range between 10 to 50 litres and the required temperatures often between 121°C to 134°C and pressures of ca. 210 kPa and 310 kPa, respectively.

A problem relating to such mini-sterilisation apparatus is that one can barely, if at all, comply with the (international) requirement of obtaining a stable ambient temperature of the sterilisation boiler during sterilisation.

The sterilisation apparatus according to the invention overcomes this problem due to the fact that the casing comprises a cylindrical horizontally arranged boiler wherein a cylindrical inner boiler is horizontally placed whereby said fluid partly fills the cylindrical space between said boilers whilst at least during the sterilisation process the upper cylindrical space is filled with steam which process is controlled by a process computer arranged in said casing. This arrangement moreover makes the sterilisation process very well manageable in a small i.e. mini-sterilisation apparatus, as has proven in practice, and above all fully comply with the requirements as mentioned.

Advantage is offered by the embodiment according to the invention wherein means are present for feeding steam for the sterilisation process pulsatingly into said inner boiler as well as means which can also provide a pulsating vacuum  
5 in said boiler such that air in the instruments or the like objects which are to be sterilised can be removed.

In order to secure the sterilisation process according to the invention means are present for setting, respectively measuring pressure, temperature, time and output for controlling  
10 all phases occurring within said boiler before, during and after the sterilisation process. These means are preferably controlled by a process computer which displays various data read-outs digitally and/or alphanumerically and/or graphically  
15 e.g. to an internal or external printing apparatus (printer).

## Claims

1. Sterilisation apparatus for medical instruments and the like objects which is easy to handle and/or remove consisting of a casing with a sterilisation chamber mainly comprising of a double-walled boiler whereby fluid such as demineralised water being present between an inner and outer wall of said boiler and means for performing the sterilisation process such as regulators and heating elements by means of which temperature and steam generated therefrom are controlled, characterized in that said casing comprises a cylindrical horizontally arranged boiler wherein a cylindrical inner boiler is horizontally placed whereby said fluid partly fills the cylindrical space between said boilers whilst at least during the sterilisation process the upper cylindrical space is filled with steam which process is controlled by a process computer arranged in said casing.
2. Apparatus according to claim 1, characterized in that means are present for feeding steam for the sterilisation process pulsatingly into said inner boiler as well as means which can also provide a pulsating vacuum in said boiler such that air in the instruments or the like objects which are to be sterilised can be removed.
3. Apparatus according to claim 1 or 2, characterized in that means are present for setting, respectively measuring pressure, temperature, time and output for controlling all phases occurring within said boiler before, during and after the sterilisation process.
4. Apparatus according to claim 1-3, characterized in that the means are controlled by a process computer which displays various data read-outs digitally and/or alphanumerically and/or graphically, e.g. to an internal or external printing apparatus (printer).

AMENDED SHEET

5. Apparatus according to any of the preceding claims, characterized in that a (time) switch clock for use of "stand-by" purposes, such as for heating-up of and maintaining the temperature of said boiler, is available.

5

6. Apparatus according to any or several of the preceding claims, characterized in that the sterilisation space of the boiler is provided with lateral supports of standard plateaus on which instruments, whether wrapped or not, and/or bandage substances can be placed.

10

7. Apparatus according to any or several of the preceding claims, characterized in that the front or entrance of the boiler is sealed pressure-tight by means of a heat-isolating hinged door provided with an incorporated nut whereby the casing to that end is provided with a swivelable hermetically sealing screw.

15

8. Apparatus according to any or several of the preceding claims, characterized in that the screw seal is operated by means of an electromotor of which the operating phases are controlled by said process computer.

20

9. Apparatus according to any or several of the preceding claims, characterized in that a cylindrical sterilation boiler is placed symmetrically though non-concentrally within said cylindrical outer boiler, such that in the use-position the volume of the fluid or water space down in the double-walled boiler is considerably larger than up in the boiler.

25

30

10. Apparatus according to any or several of the preceding claims, characterized in that the proces computer and boilers are provided in a casing in which also the fluid reservoir with corresponding pump, control appendages, a dry-air connection and a connection to a vacuum line with valves being present.

35

## Sterilisator.

De uitvinding heeft betrekking op een sterilisator voor medische instrumenten en dergelijke voorwerpen welke gemakkelijk hanteerbaar en/of verplaatsbaar is en in hoofdzaak gevormd wordt door een omkasting waarin een sterilisatieketel en middelen voor het realiseren van het sterilisatieproces aangebracht zijn.

Een dergelijke sterilisator, ook wel als mini-sterilisator aangeduid, wordt veelal in een tandartsen-praktijk gebruikt. De inhoud van de sterilisatie-ketel is daarbij tussen de 10-50 liter en liggen de vereiste temperaturen veelal tussen de 121°C en 134°C bij drukken van  $\pm$  210 resp. 310 kPa.

Een probleem bij deze mini-sterilisator is nu dat niet of nauwelijks aan de (internationale) eis kan worden voldaan om tijdens het steriliseren een stabiele omgevings-temperatuur van de sterilisator-ketel te verkrijgen.

De uitvinding nu ondervangt dit probleem doordat de sterilisator een dubbelwandige ketel omvat waarbij tussen de binnen- en buitenwand vloeistof, zoals gedemineraliseerd water, aanwezig is waarmee een stabiele temperatuur in de ketelwand bereikt kan worden alsmede stoom daaruit kan worden opgewekt. Hierdoor is het sterilisatie-proces in een relatief kleine sterilisator zeer goed beheersbaar, hetgeen de praktijk ook heeft uitgewezen.

Gunstig is het daarbij dat althans regulateurs en verwarmings-elementen in de dubbele ketelwand voor een stabiele temperatuur kunnen zorgen.

Voordeel biedt de uitvoering volgens de uitvinding waarbij middelen aanwezig zijn om stoom voor het sterilisatie-proces pulserend in de ketel te voeren alsmede middelen die eveneens pulserend vacuüm in de ketel tot stand kunnen brengen zodanig dat lucht in de te steriliseren instrumenten of dergelijke voorwerpen kan worden verwijderd.

Teneinde het sterilisatie-proces automatisch te doen plaatsvinden is de sterilisator voorzien van middelen voor het

instellen resp. vaststellen van druk, temperatuur, tijd en debiet voor het besturen van alle binnen de ketel plaatsvindende fasen vóór, gedurende en na het sterilisatie-proces. Bij voorkeur worden deze middelen bestuurd door een proces-

5 computer welke diverse gegevens digitaal en/of alfa-numeriek en/of grafisch uitleesbaar weergeeft bijv. aan een interne of externe afdrukinrichting (printer).

Vooral in de praktijk van een tandarts waarbij intensief van een autoclaaf gebruik gemaakt wordt kan het gewenst zijn om

10 een mini-sterilisator te voorzien van een (tijd-)schakelklok voor het gebruik van "stand-by" doeleinden, zoals voor het opwarmen en voor het warmhouden van de ketel.

Voordeel biedt de uitvoeringsvorm van een mini-sterilisator volgens de uitvinding welke daardoor is gekenmerkt dat de

15 sterilisatie-ruimte in de ketel voorzien is van zijdelingse draagsteunen voor een aantal standaardplateau's waarop al of niet verpakte instrumenten en/of verbandstoffen steriel verplaatsbaar zijn.

Het is voor een doeltreffend gebruik wenselijk dat bij de

20 mini-sterilisator volgens de uitvinding de voor- of invoerzijde van de ketel drukvast afsluitbaar is d.m.v. een warmte-isolerende scharnierbare deur die voorzien is van een ingebouwde moer waarbij de omkasting daartoe voorzien is van een draaibare hermetisch afsluitende schroef. Bij voorkeur wordt

25 de schroefafsluiting d.m.v. een elektromotor bediend waarvan de bedieningsfasen via de procescomputer verlopen.

Teneinde aan de vereiste procedure voor processterilisatie te voldoen wordt volgens de uitvinding gebruik gemaakt van een sterilisatie-ketel voor inbouw in een mini-sterilisator

30 die daardoor is gekenmerkt dat een cilindrische sterilisatieketel symmetrisch doch a-concentrisch binnen de cilindrische buiten-ketel is opgesteld, zodanig dat in de gebruiksstand het volume van de vloeistof- of waterruimte onderin de dubbelwandige ketel aanmerkelijk groter is dan bovenin de ketel.

Gunstig is het indien deze sterilisatie-ketel is aangebracht in een omkasting waarin eveneens het vloeistofreservoir met bijbehorende pomp, regel-appendages, een droogluchtaansluiting en een aansluiting op een vacuümleiding met ventielen aanwezig zijn.

De uitvinding zal hierna aan de hand van uitvoeringsvoorbeelden nader worden toegelicht, waarbij voordelen en andere kenmerken van de uitvinding naar voren zullen treden.

Fig. 1 toont een perspectivisch aanzicht van een mini-sterilisator;

Fig. 2 toont een blokschema van de belangrijkste operationele functies van de sterilisator;

Fig. 3 toont - volgens een computertekening - een andere uitvoeringsvorm van de sterilisator.

Figuur 1 toont in perspectief het vooraanzicht van de sterilisator in feite de omkasting 1 daarvan die in hoofdzaak een rechthoekige vorm bezit en vervaardigd is uit geschikt plaatmateriaal. De voorzijde toont een deur 2 die meer dan 120° kan worden opengedraaid en die verder goed geïsoleerd is tegen warmteverlies. Het openen en sluiten van de deur vindt automatisch plaats door het activeren van een (niet getekende) elektrische bedieningsknop. De geopende deur toont een (binnen)ketel 3 waarvan de ruimte 4 in deze uitvoeringsvorm voorzien is van vier draagplateau's 6, zgn. norm-trays, waarop de (verpakte) instrumenten of verbandstoffen steriel vervoerd kunnen worden. De ruimte 4 is daartoe voorzien van draagsteunen 5. De deur 2 die de sterilisatieruimte 4 kan afsluiten wordt in de sluitstand door een elektrisch aangedreven schroefsluiting 7 drukdicht vastgezet en kan tijdens een sterilisatieproces niet worden geopend. Tijdens een proces geeft het L.C.D. scherm 8 grafisch het verloop van dit proces weer.

De sterilisator omvat bovendien een proces-computer waarvan de besturing 9 is uitgevoerd met een aanduiding voor elke procesfase. De druk, temperatuur, sterilisatietijd, droogtijd en mogelijke storingen worden

digitaal weergegeven, alfa-numeriek eventueel grafisch ondersteund. De druk in de zgn. stoomopwekker wordt, volgens voorschrift, analoog op de indicator 10 weergegeven.

Figuur 2 toont schematisch de sterilisatie-ketel 11 met diverse appendages en regelapparatuur welke onderdelen hierna zullen worden toegelicht.

Opgemerkt wordt dat voor dezelfde onderdelen eveneens dezelfde verwijzingstekens gebruikt zullen worden.

De ketel 11 bestaat volgens de uitvinding uit een binnen- en buitenwand 3 resp. 12 waarbij de inhoud van de binnenketel tussen de 10-50 liter ligt. In de ruimte 13 van de dubbele ketelwand 3,12 is gedemineraliseerd water (demiwater) 14 toegevoerd dat zodanig verhit wordt dat aan de bovenzijde van de ketel stoom 16 tot ontstaat. Het verhitten van water vindt plaats door de verwarmings-elementen 17,18 die in de ketelruimte 13 zijn aangebracht. Voor de watervoorziening omvat de sterilisator een waterreservoir 19 waaraan een vlotter-schakelaar 20 voor de niveau-regeling is aangebracht. In deze voorziening is een toevoer-pomp 21 geschakeld waarmee water onderin de ruimte 13 van de dubbele ketelwand 3,12 kan worden aangevoerd. In het pomp-circuit is een afsluitventiel 22 voor de invoer van het water naar de ketelruimte 13 toegepast. Zoals hiervoor reeds is aangegeven zijn aan de onderzijde van de ketel 3,12 verwarmings-elementen 17,18 aangebracht waarmee het toegevoerde water kan worden verhit, zodanig dat aan de bovenzijde stoom 16 wordt gevormd ten behoeve van het sterilisatie-proces. In de onderkant van de ketel is een beveiligingschakelaar 23 met vlotteruitvoering tegen droogkoken toegepast. Aan de bovenzijde is een waterniveau-regelaar 24 aanwezig zodat steeds de juiste verhouding tussen stoom en water wordt verkregen. De opgewekte stoom 16 wordt uit de ketelruimte 13 via een stoomventiel 25 pulserend in de binnenketel 3 gevoerd. In de binnenketel 3 bevindt zich verder een temperatuuropmeter 26 alsmede een druktransmitter 27. Eenzelfde transmitter is eveneens aangebracht in de buitenketel 12. Als aan de linkerzijde van de figuur 2 het water- en stoom-



systeem is aangegeven toont de rechterzijde het vacuümsysteem. Daarbij is aan de bovenzijde van de ketel een toevoerleiding 28 toegepast waarin een beluchtingsventiel 29 voor de invoer van schone lucht bij vacuüm in de ketel wordt verkregen. Een sterielvilter 30 zorgt zekerheidshalve voor schone lucht bij toevoer naar het ventiel 29.

Volgens de uitvinding wordt pulserend vacuüm in de ketel getrokken hetgeen bereikt wordt door toepassing van een water-ejecteur systeem dat in hoofdzaak bestaat uit een ejecteur 31 welke in verbinding staat met een vacuüm-ventiel 32 dat via een leiding gekoppeld is aan de binnenketel 3. In het watersysteem van de ejecteur 31 is een koudwater-ventiel 33 opgenomen welke dient voor het opwekken van vacuüm via de ejecteur 31. Verder is een drukschakelaar 34 voor de meting van de waterdruk in het leidingsysteem toegepast, waarbij het water uit de toevoer 35 wordt afgetapt.

Hierna zal in het kort een voorbeeld van sterilisatie-proces worden toegelicht bij een temperatuur van 134 °C. Een proces kan alleen gestart worden als de deur 2 gesloten is en vangt aan met het doorstomen waarbij de ventielen 25, 33 en 32 worden geopend. De ventielen 33 en 32 van het ejecteur-systeem blijven gedurende het doorstomen geopend. Het stoomventiel 25 wordt daarbij geregeld op een druk van 120 kPa in de binnenketel 3. Gedurende een bepaalde tijd, ong. 90 sec., vindt er een continue afvoer van stoom en lucht plaats. Na deze periode van 90 sec sluit het stoomventiel 25 en start de eerste vacuüm-puls. Het pulserend verloop in het proces vindt verder plaats door het bij opvolging besturen van de betreffende ventielen, de drukopbouw alsmede de tijd in seconden, zodat binnen de gestelde periode op effectieve wijze de sterilisatie-druk en -temperatuur bereikt worden. In dit voorbeeld wordt na ong. 15 sec een temperatuur bereikt van 134°C tot max. 137°C. De drukregeling in de ketel wordt gerealiseerd door een autonoom werkend regelproces. Echter, indien tijdens het sterilisatie-proces de temperatuur en/of de druk de maximaal ingestelde waarde overschrijdt wordt het proces automa-

tisch afgebroken.

Na het sterilisatie-traject volgt het drogen van de op de plateau's 6 aanwezige voorwerpen door middel van vacuüm trekken. Daartoe wordt het stoomventiel 25 gesloten en het koud-  
5 waterventiel 33 alsmede het vacuümventiel 32 geopend, totdat een druk van 10 kPa is bereikt. Bij deze druk vangt de eigenlijke droogtijd aan, die bij dit proces (134°C) 5 min. duurt. Na het drogen wordt de ketel belucht om het vacuüm op te heffen. Indien het droogproces is beeindigd worden de ventielen  
10 32 en 33 gesloten. Wanneer de keteldruk tussen de 95-105 kPa ligt sluit het beluchtings-ventiel 29 waardoor de deur 2 kan worden geopend en kunnen de gesteriliseerde voorwerpen uit de ketelruimte 4 verwijderd worden.

Zoals hiervoor is gesteld vindt het gehele proces onder de  
15 besturing en bewaking van een computer plaats en worden de resultaten door een afdrukinrichting, zgn. printer (verder niet getekend), weergegeven.

Fig. 3 toont een andere gunstige uitvoeringsvorm volgens de uitvinding waarbij in het bijzonder door de plaatsing van de  
20 binnenketel 3 ten opzichte van de buitenketel 12 het waterreservoir 13 vergroot is, d.w.z. dat de hoeveelheid aan water in de onderzijde van de ketel 11 groter is dan aan de bovenzijde ervan, hetgeen voor bepaalde sterilisatie-processen voordelig kan zijn gezien de water-stoom verhouding.

De uitvinding beperkt zich overigens niet tot de hiervoor besproken en getoonde uitvoeringsvoorbeelden aangezien andere vormen van sterilisatie-ketels denkbaar zijn. De maatregel volgens de uitvinding om een dubbele ketelwand toe te passen in een relatief kleine sterilisator heeft echter daartoe geleid dat een dergelijke sterilisator aan de hoogste eisen -  
30 ook internationaal - kan voldoen.

## Conclusies

1. Sterilisator voor medische instrumenten en dergelijke voorwerpen welke gemakkelijk hanteerbaar en/of verplaatsbaar is en in hoofdzaak gevormd wordt door een omkasting waarin een sterilisatie-ketel en middelen voor het realiseren van het sterilisatie-proces aangebracht zijn, met het kenmerk, dat de sterilisator een dubbelwandige ketel omvat waarbij tussen de binnen- en buitenwand vloeistof, zoals gedemineraliseerd water, aanwezig is waarmee een stabiele temperatuur in de ketelwand kan worden bereikt alsmede stoom voor het sterilisatie-proces daaruit kan worden opgewekt.
2. Sterilisator volgens conclusie 1, met het kenmerk, dat althans regulateurs en verwarmings-elementen in de dubbele ketelwand voor een stabiele temperatuur van de vloeistof kunnen zorgen.
3. Sterilisator volgens conclusie 1 of 2, met het kenmerk, dat middelen aanwezig zijn om stoom voor het sterilisatie-proces pulserend in de ketel te voeren alsmede middelen die eveneens pulserend vacuüm in de ketel tot stand kunnen brengen, zodanig dat lucht in de te steriliseren medische instrumenten of dergelijke voorwerpen kan worden verwijderd.
4. Sterilisator volgens een der voorgaande conclusies 1-3, met het kenmerk, dat middelen aanwezig zijn voor het instellen resp. vaststellen van druk, temperatuur, tijd en debiet voor het besturen van alle binnen de ketel plaatsvindende fasen vóór, gedurende en na het sterilisatieproces.
5. Sterilisator volgens conclusie 4, met het kenmerk, dat de middelen bestuurd worden door een proces-computer welke diverse gegevens digitaal en/of alfa-numeriek en/of grafisch uitleesbaar weergeeft bijv. aan een interne of externe af-drukinrichting (printer).

6. Sterilisator volgens een der voorgaande conclusies, met het kenmerk, dat een (tijd-)schakelklok voor het gebruik van "stand-by" doeleinden, zoals voor het opwarmen en voor het warmhouden van de ketel, aanwezig is.

5

7. Sterilisator volgens een of meer der voorgaande conclusies, met het kenmerk, dat de sterilisatieruimte in de ketel voorzien is van zijdelingse draagsteunen voor een aantal standaardplateau's waarop al dan niet verpakte instrumenten en/of verbandstoffen steriel verplaatsbaar zijn.

10

8. Sterilisator volgens een of meer der voorgaande conclusies, met het kenmerk, dat de voorzijde van de ketel drukvast afsluitbaar is d.m.v. een warmte-isolerende scharnierbare deur die voorzien is van een ingebouwde moer waarbij de omkasting daartoe voorzien is van een draaibare hermetisch afsluitende schroef.

15

9. Sterilisator volgens conclusie 8, met het kenmerk, dat de schroefafsluiting d.m.v. een elektromotor wordt bediend, waarvan de bedieningsfasen via de procescomputer verlopen.

20

10. Sterilisator volgens een of meer der voorgaande conclusies, met het kenmerk, dat een cilindrische sterilisatieketel symmetrisch doch a-concentrisch binnen de cilindrische buitenketel is opgesteld, zodanig dat in de gebruiksstand het volume van de vloeistof- of waterruimte onderin de dubbelwandige ketel aanmerkelijk groter is dan bovenin de ketel.

25

11. Sterilisator volgens een of meer der voorgaande conclusies 1-9, met het kenmerk, dat een cilindrische sterilisatieketel concentrisch binnen een cilindrische buitenketel is opgesteld.

30

12. Sterilisator volgens een der voorgaande conclusies 1-9, waarbij de procescomputer en een sterilisatieketel volgens conclusie 10 of 11 zijn aangebracht in een omkasting waarin eveneens het vloeistofreservoir met bijbehorende pomp, een  
5 droogluchtaansluiting, regel-appendages en een aansluiting op een vacuümleiding met ventielen aanwezig zijn.

## Uittreksel

Sterilisator voor medische instrumenten en dergelijke voorwerpen welke gemakkelijk hanteerbaar en/of verplaatsbaar is en in hoofdzaak gevormd wordt door een omkasting waarin een sterilisatie-ketel en middelen voor het realiseren van het sterilisatie-proces aangebracht zijn.

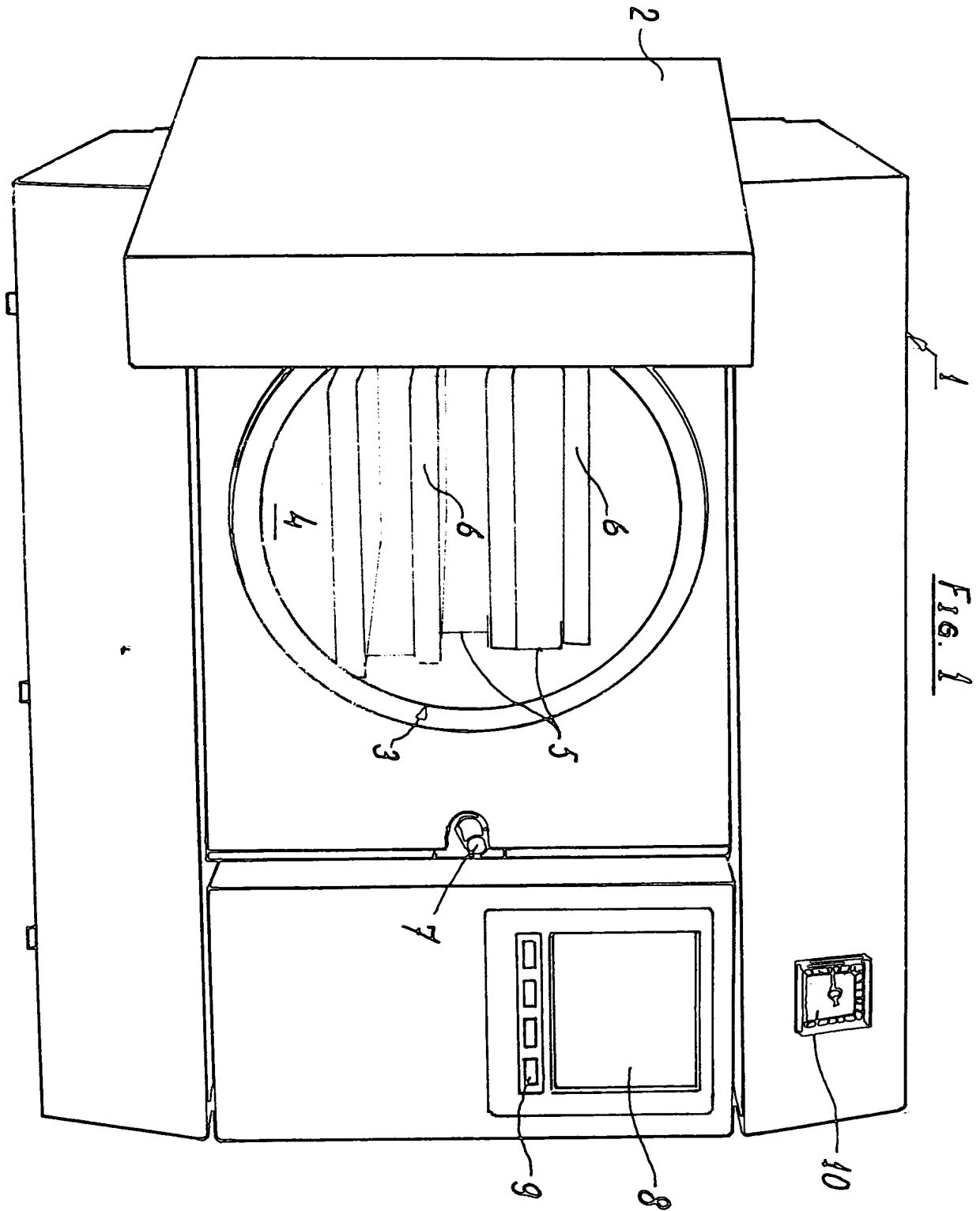
5

Volgens de uitvinding omvat de sterilisator een dubbelwandige ketel waarbij tussen de binnen- en buitenwand vloeistof, zoals gedemineraliseerd water, aanwezig is waarmee een stabiele temperatuur in de ketelwand kan worden bereikt alsmede stoom voor het sterilisatie-proces daaruit kan worden opgewekt.

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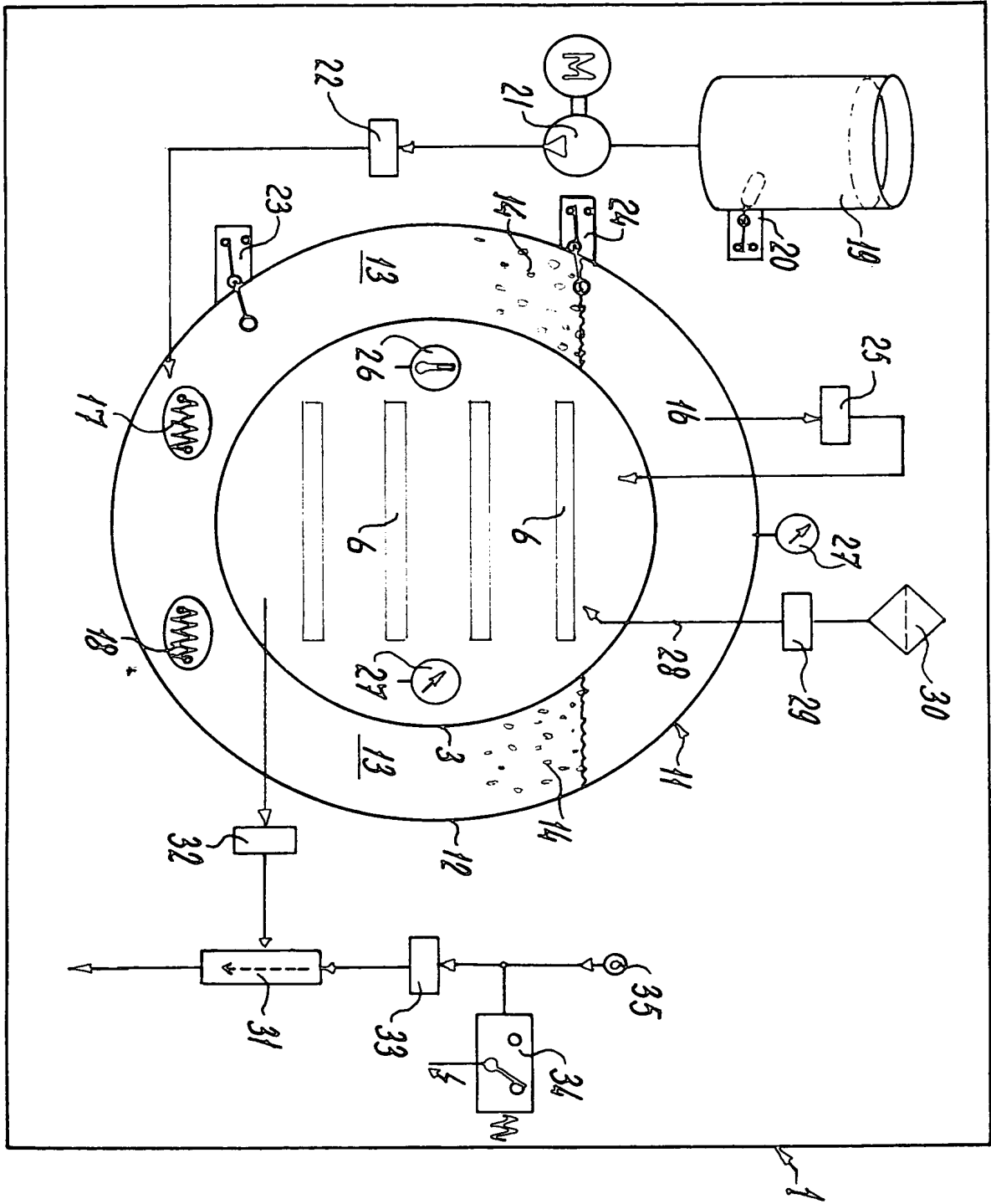


FIG. 2



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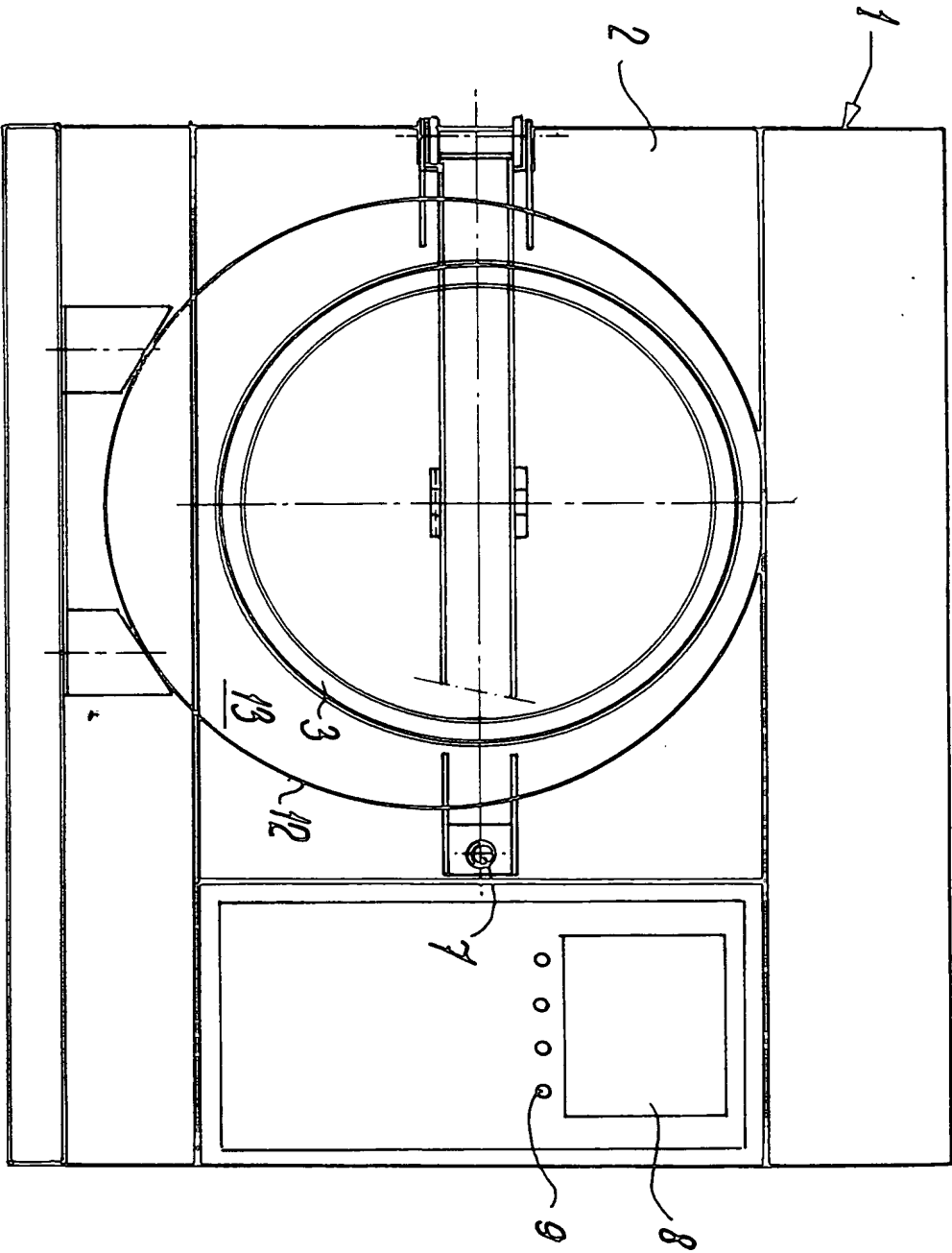


Fig. 3

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|   |   |  |
|---|---|--|
| Applicant's or agent's file reference<br><b>39810.01 nm</b> | <b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |  |
| International application No.<br><b>PCT/NL 97/ 00404</b>    | International filing date (day/month/year)<br><b>09/07/1997</b>   | (Earliest) Priority Date (day/month/year)<br><b>12/07/1996</b> |
| Applicant<br><b>HEVO N.V.</b>                               |   |  |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☐ Unity of invention is lacking (see Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
  - ☐ filed with the international application.
  - ☐ furnished by the applicant separately from the international application,
    - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - ☐ Transcribed by this Authority
4. With regard to the title,
  - ☐ the text is approved as submitted by the applicant.
  - ☒ the text has been established by this Authority to read as follows:

**STERILISATION APPARATUS**

5. With regard to the abstract,
  - ☐ the text is approved as submitted by the applicant.
  - ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
  - Figure No. 2 ☐ as suggested by the applicant. ☐ None of the figures.
  - ☐ because the applicant failed to suggest a figure.
  - ☒ because this figure better characterizes the invention.

## Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

Abstract

Sterilisation apparatus, for medical instruments and similar objects, which is easy to handle and/or remove and which is mainly formed by a casing (1) provided with a sterilisation boiler (11) and means for performing the sterilisation process.

The sterilisation apparatus comprises a double-walled boiler (11) whereby fluid (13), such as demineralised water, which is present between the inner wall (3) and the outer wall (12), is heated by heating elements (17, 18) so as to achieve a stable temperature of the boiler wall as well as to generate steam (16).

The apparatus further comprises a water reservoir (19), pump (21) and valve (22) for supplying water to the boiler and means (23,24) for controlling the level of water, a valve (25) through which generated steam (16) can be injected into the sterilisation chamber, a water-ejector (31) for drawing a vacuum in the chamber, and an aeration valve (29) for releasing the vacuum.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 97/00404

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61L2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages                           | Relevant to claim No. |
|------------|--|-----------------------|
| X          | DE 29 25 034 A (VEREINIGTE EDELSTAHLWERKE (VEW)) 7 February 1980<br>see the whole document<br>---            | 1-4                   |
| X          | FR 889 067 A (F. LAUTENSCHLÄGER) 30 December 1943<br>see the whole document<br>---                           | 1-3,7,11              |
| X          | DE 14 92 497 A (K.A.O. WALLDÉN) 2 October 1969<br>see page 11, paragraph 1 - paragraph 2;<br>figure 5<br>--- | 1,2,11                |
| X          | DE 904 237 C (F. LAUTENSCHLÄGER) 15 February 1954<br>see the whole document<br>---                           | 1,2,11                |
|            | -/-  |                       |

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## ° Special categories of cited documents :

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\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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\*Z\* document member of the same patent family

Date of the actual completion of the international search

18 November 1997

Date of mailing of the international search report

Name and mailing address of the ISA

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 97/00404

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages                                   | Relevant to claim No. |
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Information on patent family members

International Application No

PCT/NL 97/00404

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)   | Publication<br>date                                      |
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